cedures according to the EUnetHTA Core Model. To avoid any conflict of interests, no fee is paid to any member. **RESULTS:** Since 2011, three HTA reports have been completed focusing in 2011-2012 on hepatology (HCV/HBV screening and treatments) and extending in 2013 to other topics including hepatocellular carcinoma and inflammatory bowel diseases; HIV is coming up next year. Along with 4 publications in international journals (mean impact factor 5.73), there have been auditions at the Italian Drug Agency (AIFA) and at the Healthcare Commission in Parliament that have facilitated the approval of new HCV drugs. Furthermore, delays in approvals by regional formularies have been reduced by about 65% (from 212 days after national marketing authorization to 74 days; Farmindustria data). **CONCLUSIONS:** This new multidisciplinary and multistakeholder approach proved to be well-accepted, and the "WEF method" is already recognized as a milestone in the Italian HTA landscape, by both Institutions (e.g. AIFA and Italian MoH) and Scientific Societies, thus helping payers in making rational decisions based on HTA methods.

PHP160

EXPLORING THE KEY DECISION DRIVERS PROVIDED BY HTA AGENCIES ACCEPTING SUBMISSIONS WITH ICERS HIGHER THAN THE THRESHOLD

Goodrich K, Walsh SCM

HERON Evidence Development Ltd., London, UK

OBJECTIVES: Health technology assessment (HTA) agencies use an incremental cost-effectiveness ratio (ICER) threshold, generally understood to be £30,000 for NICE (England), £20,000 for the SMC (Scotland), CAN$50,000 for CADTH (Canada), and AUS$42,000 for PBAC (Australia). To help inform future submissions, we assessed the rationale provided by the four HTA agencies when submissions were accepted despite the reported ICERs being higher than these thresholds. **METHODS:** All HTA appraisals from January 2000 to May 2013 from NICE, SMC, CADTH, and PBAC were included in the analysis. Multiple technology appraisals, resubmissions, vaccination programmes, requests for advice, and submissions for which an ICER could not be determined were excluded from the analysis. The full responses of the remaining appraisals were reviewed, with the submitted ICER (with and without proposed PAS), recommendation, and reasoning behind the recommendation extracted. **RESULTS:** A total of 594 submissions met the inclusion criteria and 240 included a higher-than-threshold ICER, with 75 (31.6%) accepted. The key rationale for acceptance was a lack of alternative treatments (25/75). Submissions were also accepted based on the inclusion of a PAS (21/75), a demonstrated cost-effectiveness in a restricted patient population (16/75), and a robust economic evaluation resulting in a certain ICER (13/75). The agencies consistently based their rationale on clinical need and cost-effectiveness, although the proportions varied between the agencies: NICE (53.3%), SMC (59.4%), CADTH (70.0%), PBAC (81.8%). **CONCLUSIONS:** The majority of submissions reporting ICERs greater than the threshold ICER were rejected. ICERs over the threshold ICER were either brought in line with the threshold ICER through PASs or restricting the patient population; or accepted in spite of the high ICER based a clear clinical need or a robust and certain economic analysis. This highlights the importance for manufacturers to provide robust and appropriately justified economic evaluations, even at the expense of an ICER lower than threshold.

PHP161

ARE CONDITIONALLY APPROVED THERAPIES SUCCESSFUL IN GAINING MARKET ACCESS?

Sweeney N[1], Nijhuis T[1], Haigh J[2]

[1]*Quintiles, Hoofddorp, The Netherlands,* [2]*Quintiles, Reading, UK*

OBJECTIVES: To evaluate all medicines that received a conditional regulatory approval in Europe and to compare these decisions with the products current market access status through the evaluation of Health Technology Assessments (HTAs). **METHODS:** A manual search of the European Medicines Agencies (EMA) website was carried out to identify all pharmaceuticals that received a conditional approval (January 2007 to May 2013). Of the medicines identified, the statutory funding status was checked by reviewing the websites of the key HTA agencies in the EU 5 countries-: HAS (France), G-BA (Germany), AIFA (Italy), DGFPS (Spain) and AWMSG, NICE, SMC (UK). **RESULTS:** A total of 15 pharmaceuticals were found that had received an EMA conditional approval. Of these, 10 met the inclusion criteria and were analysed further: etravirine, everolimus, fampridine, lapatinib, ofatumumab, panitumumab, pixantrone, pazopanib, stiripentol and vandetanib. Of the 10 pharmaceuticals, a total of 50 HTA assessments were conducted by the 7 agencies, with 31 (62%) of the HTAs reaching a positive funding decision. Both NICE and AWMSG recommended only 1 of the conditionally approved drugs for funding, G-BA recommended 2, SMC 3, DGFPS 6, AIFA 6 and HAS 8. Of the 10 drugs, everolimus was the most successful and is funded by 6 (of the 7) HTA agencies. The key reasons for the success of everolimus were due to convincing efficacy (prolonging progression-free survival), combined with an economic case that was considered demonstrated despite some uncertainties. **CONCLUSIONS:** Whilst regulatory bodies recognise the need to grant marketing authorisation on the basis of less complete data, this does not necessarily mean a straight forward path through market access. Although the majority of HTA agencies did provide a positive funding decision; sound health economic evidence remains essential for new medicines to increase the chances of market access approval.

PHP162

ARE HEAD-TO-HEAD DATA NECESSARY TO GAIN REIMBURSEMENT IN THE FRENCH NATIONAL HEALTH CARE SYSTEM?

Patel A[1], Grosfeld D[1], Conti CC[2], Zaidi Q[1], Furniss SJ[3]

[1]*GfK Bridgehead, New York, NY, USA,* [2]*GfK Bridgehead, London, UK,* [3]*GfK Bridgehead, Melton Mowbray, UK*

BACKGROUND: Since December 2011, pharmaceutical companies are required by law to provide the Haute Autorité de Santé with head-to-head (H2H) data against standard of care when available to be entitled for reimbursement. However, France is a market where health authorities rarely deny reimbursement to innovative drugs but rather where list prices are lower than in comparable countries. **OBJECTIVES:** The aim of this research is to understand the impact of H2H data on the Service Médical Rendu (SMR) and Amélioration du Service Médical Rendu (ASMR) ratings following passage of the law. **METHODS:** Transparency Commission (TC) reports for new drugs or indication expansions of existing drugs published between January 1, 2012 and March 31, 2013 were reviewed. The following data were gathered: 1) study type (placebo-controlled vs active H2H comparator); 2) comparator (if H2H); 3) availability of appropriate comparators in the marketplace; and 4) SMR/ASMR ratings. **RESULTS:** A total of 110 TC assessments of 88 drugs were identified and examined. Ninety-four of the 110 assessments were of drugs where an appropriate comparator existed in the marketplace. Of these 94 assessments, H2H trials were conducted in 54 assessments. The percentage of assessments in the H2H group obtaining an SMR of important (78%) was similar to those that did not conduct H2H trials (75%). In contrast, the percentage of assessments in the H2H group obtaining an ASMR of III or IV was greater than the non-H2H group (15% vs. 26%). **CONCLUSIONS:** The conduct of H2H trials does not guarantee an SMR of important for new drugs or indication extensions, but may improve ASMR rating. Although the TC mentions the lack of comparative data as a major contributing factor for an SMR of insufficient in their assessments of some products (Daxas, Xiapex), other factors, such as adverse events or efficacy data vs placebo are equally important.

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INFLUENCE OF PATIENT-REPORTED OUTCOMES ON HTA REIMBURSEMENT DECISIONS

Kulich K[1], Versoza L[2], Jaksa A[2], Demuro-Mercon C[3], Gnanasakthy A[4]

[1]*Novartis Pharma AG, Basel, Switzerland,* [2]*Context Matters, Inc., New York, NY, USA,* [3]*RTI Health Solutions, Research Triangle Park, NC, USA,* [4]*Novartis Pharmaceuticals, East Hanover, NJ, USA*

OBJECTIVES: To understand how patient-reported outcomes (PROs) influence decisions made by Health Technology Assessment (HTA) agencies. **METHODS:** Reports from five HTA agencies that make reimbursement decisions (NICE, HAS, SMC, PBAC and CADTH's CDR) were selected. The reports, taken from January 2005-April 2013, cover disease conditions in neurological and respiratory therapeutic areas. PROs within the HTA reports were identified and four analysts independently examined the stated rationales for the agencies' decisions to determine whether PROs had a positive, negative, or neutral influence on the decision. Discrepancies between the analysts were discussed in-depth until consensus was reached. **RESULTS:** A total of 262 HTA reports were analyzed from the five agencies selected. PROs were mentioned in 34% of the HTA reports, and were the primary endpoint in 6%. Twenty-five (10%) reports mentioned PRO in the clinical rationale for their decisions. Twelve of the 25 HTA reports (48%) contained PRO as a primary outcome, indicating that a PRO is more likely to influence the decision-making process if it is a primary outcome ($p < 0.001$). In 12 out of the 25 HTA reports, the clinical rationale for the decision stated that, for the PRO, the drug performed better than placebo or comparator. Ten (83%) of these reports resulted in a positive decision. In eight reports, the drug compared equivalently or unfavorably to placebo or comparator for the PRO and resulted in four (50%) positive decisions. There was no significant difference in agency decisions between the reports that positively reported PROs and the reports with negative or similar PRO results ($p=0.16$). **CONCLUSIONS:** In respiratory and neurological diseases, the use of PROs is more likely to influence decision-making by HTA agency when PROs are specified as primary outcomes. Future research directions include comparing these findings to the effect other clinical outcomes have on reimbursement decisions.

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HEALTH ECONOMIC (HE) DATA REQUIREMENTS AND AVAILABILITY IN THE EUROPEAN UNION. RESULTS OF A SURVEY

Skoupa J[1], Annemans L[2], Hájek P[3]

[1]*1st Medical Faculty, Charles University, Prague, Czech Republic,* [2]*Ghent University & Brussels University, Ghent, Belgium,* [3]*Pfizer, Praha, Czech Republic*

OBJECTIVES: To compare data requirements and their availability for HE evaluations in 5 countries in Central/Eastern Europe - Poland, Czech Republic, Slovakia, Hungary, Romania (CEE) and 5 in Western Europe – UK, France, Germany, The Netherlands, Sweden (WE). **METHODS:** A questionnaire was developed and distributed to market access representatives from Pfizer who were asked to complete the questionnaire with opinion leader's support. The questionnaire focused on the obligation to conduct HE assessment for reimbursement submissions, local HE guidelines, applied discount rates for future costs and effects, willingness to pay (WTP) thresholds and available data sources. **RESULTS:** HE is mandatory in all CEE and 3 WE participating countries for reimbursement applications of innovative drugs. Usually cost-effectiveness (CEA) and budget-impact (BIA) analyses are required. The preferred outcome of CEA is quality-adjusted-life years. In Romania, France and Czech Republic guidelines could not be identified at the time of the survey. HE evaluations are usually prepared by the applicant; in Sweden, UK, The Netherlands and Poland unlocked models have to be presented for scrutiny. Discount rates vary from 1.5% to 5%; usually the same for costs and outcomes (except in The Netherlands and Poland). Only UK, Poland and Slovakia have an explicit WTP threshold. In Poland it is based on GDP per capita, in Slovakia on multiples of average monthly wages. Differences were found on data availability. In WE data can be acquired easier compared to CEE. Health insurance funds do not provide their data, unless they were published. Patient registries are either not available in CEE or difficult to access, so applicants mostly rely on retrospective medical chart data, hospital information systems or expert panels. **CONCLUSIONS:** We found similar requirements for HE analyses in CEE and WE but differences in data availability. This results in less accurate inputs across the CEE influencing analyses' outcomes.

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KEY DRIVERS OF PBAC DECISIONS FOR THE REIMBURSEMENT OF ORPHAN DRUGS ON THE LIFE SAVING DRUGS PROGRAM

Maguire B, Tilden D

THEMA Consulting Pty. Limited, Pyrmont, Australia